Clinical trial results:
A phase 2, open-label, single-arm, multicenter study of SOT101 in combination with pembrolizumab to evaluate the efficacy and safety in patients with selected advanced/refractory solid tumors

Summary

EudraCT number	2021-005774-25
Trial protocol	FR ES CZ BE IT HU PL
Global end of trial date	28 November 2024

Results information

Result version number	v1 (current)
This version publication date	31 August 2025
First version publication date	31 August 2025

Trial information

Trial identification

Sponsor protocol code	SC104 (AURELIO-04)

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05256381
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 140011

Notes:

Sponsors

Sponsor organisation name	SOTIO Biotech AG
Sponsor organisation address	Lichtstrasse 35 - WSJ-210, Basel, Switzerland, 4056
Public contact	Clinical trials, SOTIO Biotech AG, +420 224 175 111, clinicaltrial@sotio.com
Scientific contact	Clinical trials, SOTIO Biotech AG, +420 224 175 111, clinicaltrial@sotio.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 November 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 November 2024
Global end of trial reached?	Yes
Global end of trial date	28 November 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To estimate the antitumor efficacy of nanrilkefusp alfa in combination with pembrolizumab

Protection of trial subjects:

Not applicable

Background therapy:

Pembrolizumab 200 mg was administered as an intravenous infusion via peripheral or central venous line within 30 minutes after the first dose (day 1) of nanrilkefusp alfa in each 21-day cycle.

Evidence for comparator:

Not applicable

Actual start date of recruitment	21 June 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Georgia: 56
Country: Number of subjects enrolled	United States: 4
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Spain: 45
Country: Number of subjects enrolled	Belgium: 19
Country: Number of subjects enrolled	Czechia: 8
Country: Number of subjects enrolled	France: 21
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Italy: 8
Worldwide total number of subjects	165
EEA total number of subjects	105

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	72
From 65 to 84 years	93
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Not applicable

Pre-assignment

Screening details:

Forty-one investigational sites participated in study SC104 and screened at least 1 patient (8 sites in Georgia, 9 sites in Spain, 8 sites in France, 4 sites in Belgium, 3 sites in the Czech Republic, 1 site in the U.S., 5 sites in Italy, 2 sites in Hungary, 1 site in Poland).

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Non-small cell lung cancer

Arm description:

Advanced and/or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after an immune checkpoint inhibitor-containing regimen and a platinum-containing regimen, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, and who were not amenable to curative treatment

Arm type	Experimental
Investigational medicinal product name	Nanrilkefusp alfa
Investigational medicinal product code	SOT101
Other name	SO-C101, RLI-15
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

Nanrilkefusp alfa 12 µg/kg was administered subcutaneously on day 1 (±1 day for the cycle start), day 2, day 8, and day 9 of each 21-day cycle.

Arm title	Colorectal cancer

Arm description:

Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer that was unresectable or metastatic

Arm type	Experimental
Investigational medicinal product name	Nanrilkefusp alfa
Investigational medicinal product code	SOT101
Other name	SO-C101, RLI-15
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

Nanrilkefusp alfa 12 µg/kg was administered subcutaneously on day 1 (±1 day for the cycle start), day 2, day 8, and day 9 of each 21-day cycle.

Arm title	Cutaneous squamous cell carcinoma

Arm description:

Recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that was not curable by surgery or radiation and in second line if refractory or relapsed after a checkpoint inhibitor-containing regimen and radiotherapy was not feasible

Arm type	Experimental

Investigational medicinal product name	Nanrilkefusp alfa
Investigational medicinal product code	SOT101
Other name	SO-C101, RLI-15
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

Nanrilkefusp alfa 12 µg/kg was administered subcutaneously on day 1 (±1 day for the cycle start), day 2, day 8, and day 9 of each 21-day cycle.

Arm title	Hepatocellular carcinoma

Arm description:

Advanced hepatocellular carcinoma after recurrence or failure of an immune checkpoint inhibitor (not applicable in France)

Arm type	Experimental
Investigational medicinal product name	Nanrilkefusp alfa
Investigational medicinal product code	SOT101
Other name	SO-C101, RLI-15
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

Nanrilkefusp alfa 12 µg/kg was administered subcutaneously on day 1 (±1 day for the cycle start), day 2, day 8, and day 9 of each 21-day cycle.

Arm title	Metastatic castration-resistant prostate cancer

Arm description:

Treatment-refractory metastatic castration-resistant prostate cancer (mCRPC) after recurrence or failure of docetaxel and prior treatment with abiraterone, enzalutamide, or any other androgen receptor-targeted agent

Arm type	Experimental
Investigational medicinal product name	Nanrilkefusp alfa
Investigational medicinal product code	SOT101
Other name	SO-C101, RLI-15
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

Nanrilkefusp alfa 12 µg/kg was administered subcutaneously on day 1 (±1 day for the cycle start), day 2, day 8, and day 9 of each 21-day cycle.

Arm title	Ovarian cancer

Arm description:

Advanced recurrent ovarian cancer after recurrence or failure on the last platinum-based therapy within 6 months

Arm type	Experimental
Investigational medicinal product name	Nanrilkefusp alfa
Investigational medicinal product code	SOT101
Other name	SO-C101, RLI-15
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

Nanrilkefusp alfa 12 µg/kg was administered subcutaneously on day 1 (±1 day for the cycle start), day 2, day 8, and day 9 of each 21-day cycle.

Number of subjects in period 1	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma
Started	40	8	12
Completed	0	0	0
Not completed	40	8	12
Consent withdrawn by subject	4	-	2
Physician decision	-	-	1
Death	17	3	4
Other	-	-	-
Study terminated by sponsor	18	5	5
Lost to follow-up	1	-	-

Number of subjects in period 1	Hepatocellular carcinoma	Metastatic castration-resistant prostate cancer	Ovarian cancer
Started	12	54	39
Completed	0	0	0
Not completed	12	54	39
Consent withdrawn by subject	2	8	6
Physician decision	-	2	-
Death	5	24	21
Other	-	1	1
Study terminated by sponsor	5	18	11
Lost to follow-up	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Non-small cell lung cancer
Reporting group description:	
Advanced and/or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after an immune checkpoint inhibitor-containing regimen and a platinum-containing regimen, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, and who were not amenable to curative treatment	
Reporting group title	Colorectal cancer
Reporting group description:	
Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer that was unresectable or metastatic	
Reporting group title	Cutaneous squamous cell carcinoma
Reporting group description:	
Recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that was not curable by surgery or radiation and in second line if refractory or relapsed after a checkpoint inhibitor-containing regimen and radiotherapy was not feasible	
Reporting group title	Hepatocellular carcinoma
Reporting group description:	
Advanced hepatocellular carcinoma after recurrence or failure of an immune checkpoint inhibitor (not applicable in France)	
Reporting group title	Metastatic castration-resistant prostate cancer
Reporting group description:	
Treatment-refractory metastatic castration-resistant prostate cancer (mCRPC) after recurrence or failure of docetaxel and prior treatment with abiraterone, enzalutamide, or any other androgen receptor-targeted agent	
Reporting group title	Ovarian cancer
Reporting group description:	
Advanced recurrent ovarian cancer after recurrence or failure on the last platinum-based therapy within 6 months	

Reporting group values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma
Number of subjects	40	8	12
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	23	5	1
From 65-84 years	17	3	11
85 years and over	0	0	0
Age continuous Units: years			
median	63.5	59.0	75.5
standard deviation	± 10.43	± 18.34	± 10.95

Gender categorical Units: Subjects			
Female	12	3	2
Male	28	5	10

Reporting group values	Hepatocellular carcinoma	Metastatic castration-resistant prostate cancer	Ovarian cancer
Number of subjects	12	54	39
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	8	14	21
From 65-84 years	4	40	18
85 years and over	0	0	0
Age continuous Units: years			
median	63.5	68.0	64.0
standard deviation	± 11.02	± 6.57	± 11.59
Gender categorical Units: Subjects			
Female	1	0	39
Male	11	54	0

Reporting group values	Total		
Number of subjects	165		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	72		
From 65-84 years	93		
85 years and over	0		
Age continuous Units: years			
median			
standard deviation	-		
Gender categorical Units: Subjects			
Female	57		
Male	108		

Subject analysis sets	
Subject analysis set title	Efficacy population
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

The efficacy population consisted of all patients exposed to the combination therapy for at least one treatment cycle. This was defined as patients with 4 doses of nanrilkefusp alfa and 1 dose of pembrolizumab in Cycle 1, or patients exposed to both nanrilkefusp alfa and pembrolizumab in Cycle 1 who started Cycle 2.

Subject analysis set title	All-subjects-as-treated population
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

The all-subjects-as-treated (ASaT) population consisted of all patients exposed to nanrilkefusp alfa or pembrolizumab.

Reporting group values	Efficacy population	All-subjects-as-treated population	
Number of subjects	154	165	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	67	72	
From 65-84 years	87	93	
85 years and over	0	0	
Age continuous Units: years			
median	66.0	66.0	
standard deviation	± 11.01	± 10.90	
Gender categorical Units: Subjects			
Female	53	57	
Male	101	108	

End points

End points reporting groups

Reporting group title	Non-small cell lung cancer
Reporting group description:	
Advanced and/or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after an immune checkpoint inhibitor-containing regimen and a platinum-containing regimen, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, and who were not amenable to curative treatment	
Reporting group title	Colorectal cancer
Reporting group description:	
Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer that was unresectable or metastatic	
Reporting group title	Cutaneous squamous cell carcinoma
Reporting group description:	
Recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that was not curable by surgery or radiation and in second line if refractory or relapsed after a checkpoint inhibitor-containing regimen and radiotherapy was not feasible	
Reporting group title	Hepatocellular carcinoma
Reporting group description:	
Advanced hepatocellular carcinoma after recurrence or failure of an immune checkpoint inhibitor (not applicable in France)	
Reporting group title	Metastatic castration-resistant prostate cancer
Reporting group description:	
Treatment-refractory metastatic castration-resistant prostate cancer (mCRPC) after recurrence or failure of docetaxel and prior treatment with abiraterone, enzalutamide, or any other androgen receptor-targeted agent	
Reporting group title	Ovarian cancer
Reporting group description:	
Advanced recurrent ovarian cancer after recurrence or failure on the last platinum-based therapy within 6 months	
Subject analysis set title	Efficacy population
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
The efficacy population consisted of all patients exposed to the combination therapy for at least one treatment cycle. This was defined as patients with 4 doses of nanrilkefusp alfa and 1 dose of pembrolizumab in Cycle 1, or patients exposed to both nanrilkefusp alfa and pembrolizumab in Cycle 1 who started Cycle 2.	
Subject analysis set title	All-subjects-as-treated population
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
The all-subjects-as-treated (ASaT) population consisted of all patients exposed to nanrilkefusp alfa or pembrolizumab.	

Primary: Objective response rate according to RECIST 1.1

End point title	Objective response rate according to RECIST 1.1[1]
End point description:	
End point type	Primary
End point timeframe:	
Day 1 up to approximately 3 years	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses were planned for this end point

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Percentage				
number (confidence interval 95%)	5.1 (0.6 to 17.3)	33.3 (4.3 to 77.7)	27.3 (6.0 to 61.0)	0 (0 to 28.5)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Percentage				
number (confidence interval 95%)	10.0 (2.8 to 23.7)	11.4 (3.2 to 26.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of patients with a treatment-emergent adverse event

End point title	Number of patients with a treatment-emergent adverse event

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	8	12	12
Units: Patients	40	8	12	12

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	39		
Units: Patients	54	39		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of patients with an adverse event of special interest

End point title	Number of patients with an adverse event of special interest

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	8	12	12
Units: Patients	0	1	0	0

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	39		
Units: Patients	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate according to iRECIST

End point title	Objective response rate according to iRECIST

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Percentage				
number (confidence interval 95%)	7.7 (1.6 to 20.9)	33.3 (4.3 to 77.7)	36.4 (10.9 to 69.2)	0 (0 to 28.5)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Percentage				
number (confidence interval 95%)	12.5 (4.2 to 26.8)	11.4 (3.2 to 26.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to RECIST 1.1: complete response

End point title	Best overall response according to RECIST 1.1: complete response

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	0	0	1	0

End point values	Metastatic castration-	Ovarian cancer		

	resistant prostate cancer			
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to RECIST 1.1: partial response

End point title	Best overall response according to RECIST 1.1: partial response

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	2	2	2	0

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	4	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to RECIST 1.1: stable disease

End point title	Best overall response according to RECIST 1.1: stable disease

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	12	3	2	5

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	14	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to RECIST 1.1: progressive disease

End point title	Best overall response according to RECIST 1.1: progressive disease

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	20	1	6	5

End point values	Metastatic castration-resistant	Ovarian cancer		

	prostate cancer			
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	18	23		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to iRECIST: complete response

End point title	Best overall response according to iRECIST: complete response

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	0	0	1	0

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to iRECIST: partial response

End point title	Best overall response according to iRECIST: partial response

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	3	2	3	0

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	5	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to iRECIST: stable disease

End point title	Best overall response according to iRECIST: stable disease

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	15	3	2	5

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	15	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to iRECIST: unconfirmed progressive disease

End point title	Best overall response according to iRECIST: unconfirmed progressive disease

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	13	0	3	4

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	14	15		

Statistical analyses

No statistical analyses for this end point

Secondary: Best overall response according to iRECIST: confirmed progressive disease

End point title	Best overall response according to iRECIST: confirmed progressive disease

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Patients	3	1	2	1

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Patients	2	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response according to RECIST 1.1

End point title	Duration of response according to RECIST 1.1

End point description:

10: Not reached
0 or 100: Not estimable

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: months				
median (confidence interval 95%)	3.6 (1.7 to 100)	10 (0 to 100)	10 (2.8 to 100)	0 (0 to 0)

End point values	Metastatic	Ovarian cancer		

	castration-resistant prostate cancer			
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: months				
median (confidence interval 95%)	10 (4.3 to 100)	3.0 (2.8 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response according to iRECIST

End point title	Duration of response according to iRECIST
End point description: 10: Not reached 0 or 100: Not estimable	
End point type	Secondary
End point timeframe: Day 1 up to approximately 3 years	

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: months				
median (confidence interval 95%)	3.6 (1.7 to 100)	10 (0 to 100)	10 (2.8 to 100)	0 (0 to 0)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: months				
median (confidence interval 95%)	13.9 (4.3 to 100)	3.0 (2.8 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical benefit rate according to RECIST 1.1

End point title	Clinical benefit rate according to RECIST 1.1

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Percentage				
number (confidence interval 95%)	35.9 (21.2 to 52.8)	83.3 (35.9 to 99.6)	45.5 (16.7 to 76.6)	45.5 (16.7 to 76.6)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Percentage				
number (confidence interval 95%)	45.0 (29.3 to 61.5)	22.9 (10.4 to 40.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical benefit rate according to iRECIST

End point title	Clinical benefit rate according to iRECIST

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: Percentage				
number (confidence interval 95%)	46.2 (30.1 to 62.8)	83.3 (35.9 to 99.6)	54.5 (23.4 to 83.3)	45.5 (16.7 to 76.6)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: Percentage				
number (confidence interval 95%)	50.0 (33.8 to 66.2)	22.9 (10.4 to 40.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival according to RECIST 1.1

End point title	Progression-free survival according to RECIST 1.1
End point description: 10: Not reached 0 or 100: Not estimable	
End point type	Secondary
End point timeframe: Day 1 up to approximately 3 years	

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: months				
median (confidence interval 95%)	1.6 (1.3 to 2.8)	10 (1.1 to 100)	1.4 (1.2 to 100)	2.7 (1.1 to 4.3)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: months				
median (confidence interval 95%)	2.6 (1.4 to 6.4)	1.6 (1.4 to 2.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival according to iRECIST

End point title	Progression-free survival according to iRECIST
End point description: 10: Not reached 0 or 100: Not estimable	
End point type	Secondary
End point timeframe: Day 1 up to approximately 3 years	

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: months				
median (confidence interval 95%)	3.0 (1.3 to 5.7)	10 (1.1 to 100)	4.1 (1.2 to 100)	2.7 (1.1 to 4.3)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: months				
median (confidence interval 95%)	4.6 (1.6 to 6.8)	1.6 (1.4 to 2.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response according to RECIST 1.1

End point title	Time to response according to RECIST 1.1

End point description: 10: Not reached 0 or 100: Not estimable	
End point type	Secondary
End point timeframe: Day 1 up to approximately 3 years	

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: months				
median (confidence interval 95%)	10 (0 to 100)	14.1 (1.6 to 100)	10 (1.4 to 100)	10 (0 to 100)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: months				
median (confidence interval 95%)	10 (0 to 100)	10 (6.9 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response according to iRECIST

End point title	Time to response according to iRECIST
End point description: 10: Not reached 0 or 100: Not estimable	
End point type	Secondary
End point timeframe: Day 1 up to approximately 3 years	

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	6	11	11
Units: months				
median (confidence interval 95%)	10 (0 to 100)	14.1 (1.6 to 100)	10 (1.4 to 100)	10 (0 to 100)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	35		
Units: months				
median (confidence interval 95%)	10 (0 to 100)	10 (6.9 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1

End point title	Duration of response according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1[2]
End point description:	
10: Not reached 0 or 100: Not estimable	
End point type	Secondary
End point timeframe:	
Day 1 up to approximately 3 years	

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is applicable only in patients with metastatic castration-resistant prostate cancer

End point values	Metastatic castration-resistant prostate cancer			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: months				
median (confidence interval 95%)	10 (4.3 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical benefit rate according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1

End point title	Clinical benefit rate according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1[3]

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is applicable only in patients with metastatic castration-resistant prostate cancer

End point values	Metastatic castration-resistant prostate cancer			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: Percentage				
number (confidence interval 95%)	45.0 (29.3 to 61.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1

End point title	Progression-free survival according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1[4]

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 3 years

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is applicable only in patients with metastatic castration-resistant prostate cancer

End point values	Metastatic castration-resistant prostate cancer			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: months				

median (confidence interval 95%)	2.6 (1.4 to 6.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Circulating tumor cell count conversion as assessed according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1

End point title	Circulating tumor cell count conversion as assessed according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1[5]

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 2 years

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is applicable only in patients with metastatic castration-resistant prostate cancer

End point values	Metastatic castration-resistant prostate cancer			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: Percentage				
number (confidence interval 95%)	3.8 (0.5 to 13.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Confirmed prostate-specific antigen decline of ≥50% as assessed according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1

End point title	Confirmed prostate-specific antigen decline of ≥50% as assessed according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1[6]

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 2 years

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is applicable only in patients with metastatic castration-resistant prostate cancer

End point values	Metastatic castration-resistant prostate cancer			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: Percentage				
number (confidence interval 95%)	13.5 (5.8 to 26.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to confirmed prostate-specific antigen progression as assessed according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1

End point title	Time to confirmed prostate-specific antigen progression as assessed according to Prostate Cancer Clinical Trials Working Group 3 modified RECIST 1.1[7]

End point description:

End point type	Secondary

End point timeframe:

Day 1 up to approximately 2 years

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is applicable only in patients with metastatic castration-resistant prostate cancer

End point values	Metastatic castration-resistant prostate cancer			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: months				
median (confidence interval 95%)	2.3 (1.3 to 4.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Nanrilkefusp alfa concentration profile, Cycle 1 Day 1, 30 (+/-5) minutes after nanrilkefusp alfa administration

End point title	Nanrilkefusp alfa concentration profile, Cycle 1 Day 1, 30 (+/-5) minutes after nanrilkefusp alfa administration

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1, 30 (+/-5) minutes after nanrilkefusp alfa administration

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	8	12	12
Units: ng/mL				
median (full range (min-max))	1.0900 (0.260 to 3.850)	0.5890 (0.487 to 4.530)	0.7200 (0.363 to 5.580)	0.9470 (0.358 to 3.460)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	38		
Units: ng/mL				
median (full range (min-max))	0 (0 to 4.370)	0.9020 (0.151 to 3.690)		

Statistical analyses

No statistical analyses for this end point

Secondary: Nanrilkefusp alfa concentration profile, Cycle 1 Day 1, 2 hours (+/-15 minutes) after nanrilkefusp alfa administration

End point title	Nanrilkefusp alfa concentration profile, Cycle 1 Day 1, 2 hours (+/-15 minutes) after nanrilkefusp alfa administration

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1, 2 hours (+/-15 minutes) after nanrilkefusp alfa administration

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	8	12	12
Units: ng/mL				
median (full range (min-max))	3.6800 (0.628 to 15.600)	3.6700 (1.220 to 11.900)	3.4250 (1.350 to 19.100)	2.5600 (0.820 to 4.070)

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	38		
Units: ng/mL				
median (full range (min-max))	3.4500 (0.291 to 15.800)	3.1300 (0.288 to 10.700)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of patients with anti-drug antibodies, Cycle 4 Day 1

End point title	Number of patients with anti-drug antibodies, Cycle 4 Day 1

End point description:

End point type	Secondary

End point timeframe:

Cycle 4 Day 1

End point values	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma	Hepatocellular carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	8	12	12
Units: Patients	5	3	3	0

End point values	Metastatic castration-resistant prostate cancer	Ovarian cancer		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	39		
Units: Patients	4	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs): from study treatment start to 90 days after study treatment end or to new anti-cancer therapy start; related serious AEs: collected beyond 90 days after study treatment end; deaths: consent signature to study end

Adverse event reporting additional description:

Only treatment-emergent AEs (TEAEs) were analyzed (see the definition above); the tables include information on TEAEs, serious TEAEs, and all deaths; causality was assessed by investigators

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Non-small cell lung cancer

Reporting group description:

Advanced and/or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after an immune checkpoint inhibitor-containing regimen and a platinum-containing regimen, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, and who are not amenable to curative treatment

Reporting group title	Colorectal cancer

Reporting group description:

Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer that is unresectable or metastatic

Reporting group title	Cutaneous squamous cell carcinoma

Reporting group description:

Recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation and in second line if refractory or relapsed after a checkpoint inhibitor-containing regimen and radiotherapy is not feasible

Reporting group title	Hepatocellular carcinoma

Reporting group description:

Advanced hepatocellular carcinoma after recurrence or failure of an immune checkpoint inhibitor (not applicable in France)

Reporting group title	Metastatic castration-resistant prostate cancer

Reporting group description:

Treatment-refractory metastatic castration-resistant prostate cancer (mCRPC) after recurrence or failure of docetaxel and prior treatment with abiraterone, enzalutamide, or any other androgen receptor-targeted agent

Reporting group title	Ovarian cancer

Reporting group description:

Advanced recurrent ovarian cancer after recurrence or failure on the last platinum-based therapy within 6 months

Serious adverse events	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 40 (57.50%)	3 / 8 (37.50%)	3 / 12 (25.00%)
number of deaths (all causes)	17	3	4
number of deaths resulting from adverse events	11	2	2

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	5 / 40 (12.50%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 1
Cancer pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	4 / 40 (10.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			

subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Discomfort			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 40 (5.00%)	1 / 8 (12.50%)	3 / 12 (25.00%)
occurrences causally related to treatment / all	6 / 6	1 / 1	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	2 / 40 (5.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatinine increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte count decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 40 (0.00%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Myocarditis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary dilatation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal failure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal sepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Hepatocellular carcinoma	Metastatic castration-resistant prostate cancer	Ovarian cancer
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 12 (25.00%)	28 / 54 (51.85%)	28 / 39 (71.79%)
number of deaths (all causes)	5	24	21
number of deaths resulting from adverse events	1	10	12
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			

subjects affected / exposed	0 / 12 (0.00%)	7 / 54 (12.96%)	6 / 39 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 6	0 / 6
Cancer pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 54 (5.56%)	8 / 39 (20.51%)
occurrences causally related to treatment / all	0 / 0	7 / 7	14 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 12 (8.33%)	3 / 54 (5.56%)	3 / 39 (7.69%)
occurrences causally related to treatment / all	1 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 2
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	3 / 39 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2

Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 12 (8.33%)	7 / 54 (12.96%)	7 / 39 (17.95%)
occurrences causally related to treatment / all	3 / 3	9 / 9	7 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 54 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			

subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myocarditis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	2 / 54 (3.70%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary dilatation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	2 / 54 (3.70%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal failure			
subjects affected / exposed	0 / 12 (0.00%)	2 / 54 (3.70%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 54 (3.70%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 54 (3.70%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 12 (8.33%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal sepsis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 54 (1.85%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 54 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Non-small cell lung cancer	Colorectal cancer	Cutaneous squamous cell carcinoma
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 40 (100.00%)	8 / 8 (100.00%)	12 / 12 (100.00%)
Investigations			
Lymphocyte count decreased			

subjects affected / exposed	17 / 40 (42.50%)	5 / 8 (62.50%)	4 / 12 (33.33%)
occurrences (all)	26	10	10
Aspartate aminotransferase increased			
subjects affected / exposed	15 / 40 (37.50%)	3 / 8 (37.50%)	1 / 12 (8.33%)
occurrences (all)	23	4	1
Alanine aminotransferase increased			
subjects affected / exposed	14 / 40 (35.00%)	2 / 8 (25.00%)	1 / 12 (8.33%)
occurrences (all)	22	3	1
Blood bilirubin increased			
subjects affected / exposed	5 / 40 (12.50%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences (all)	6	3	0
Neutrophil count decreased			
subjects affected / exposed	1 / 40 (2.50%)	2 / 8 (25.00%)	2 / 12 (16.67%)
occurrences (all)	3	7	5
Platelet count decreased			
subjects affected / exposed	3 / 40 (7.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Blood creatinine increased			
subjects affected / exposed	4 / 40 (10.00%)	1 / 8 (12.50%)	2 / 12 (16.67%)
occurrences (all)	5	2	2
Blood alkaline phosphatase increased			
subjects affected / exposed	8 / 40 (20.00%)	1 / 8 (12.50%)	1 / 12 (8.33%)
occurrences (all)	11	1	1
Amylase increased			
subjects affected / exposed	3 / 40 (7.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Weight decreased			
subjects affected / exposed	5 / 40 (12.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	5	0	0
Lipase increased			
subjects affected / exposed	4 / 40 (10.00%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences (all)	5	1	0
Vascular disorders			
Hypotension			

subjects affected / exposed	9 / 40 (22.50%)	2 / 8 (25.00%)	2 / 12 (16.67%)
occurrences (all)	11	4	7
Hypertension			
subjects affected / exposed	4 / 40 (10.00%)	0 / 8 (0.00%)	2 / 12 (16.67%)
occurrences (all)	4	0	2
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 40 (15.00%)	1 / 8 (12.50%)	1 / 12 (8.33%)
occurrences (all)	6	3	5
Tremor			
subjects affected / exposed	4 / 40 (10.00%)	1 / 8 (12.50%)	0 / 12 (0.00%)
occurrences (all)	5	1	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	26 / 40 (65.00%)	4 / 8 (50.00%)	10 / 12 (83.33%)
occurrences (all)	114	40	30
Chills			
subjects affected / exposed	15 / 40 (37.50%)	3 / 8 (37.50%)	3 / 12 (25.00%)
occurrences (all)	20	12	11
Fatigue			
subjects affected / exposed	15 / 40 (37.50%)	1 / 8 (12.50%)	3 / 12 (25.00%)
occurrences (all)	16	1	4
Injection site reaction			
subjects affected / exposed	11 / 40 (27.50%)	3 / 8 (37.50%)	2 / 12 (16.67%)
occurrences (all)	48	9	3
Asthenia			
subjects affected / exposed	12 / 40 (30.00%)	1 / 8 (12.50%)	4 / 12 (33.33%)
occurrences (all)	12	1	6
Oedema peripheral			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Chest pain			

subjects affected / exposed	5 / 40 (12.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	5	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	17 / 40 (42.50%)	1 / 8 (12.50%)	1 / 12 (8.33%)
occurrences (all)	23	1	3
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	6 / 40 (15.00%)	2 / 8 (25.00%)	2 / 12 (16.67%)
occurrences (all)	23	10	4
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	11 / 40 (27.50%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	14	0	1
Nausea			
subjects affected / exposed	10 / 40 (25.00%)	1 / 8 (12.50%)	2 / 12 (16.67%)
occurrences (all)	18	19	2
Diarrhoea			
subjects affected / exposed	5 / 40 (12.50%)	1 / 8 (12.50%)	1 / 12 (8.33%)
occurrences (all)	8	8	1
Constipation			
subjects affected / exposed	3 / 40 (7.50%)	0 / 8 (0.00%)	2 / 12 (16.67%)
occurrences (all)	3	0	2
Abdominal pain			
subjects affected / exposed	2 / 40 (5.00%)	1 / 8 (12.50%)	1 / 12 (8.33%)
occurrences (all)	3	1	1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	7 / 40 (17.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	7	0	0
Cough			
subjects affected / exposed	6 / 40 (15.00%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	8	0	2
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	3 / 40 (7.50%)	1 / 8 (12.50%)	1 / 12 (8.33%)
occurrences (all)	4	1	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 40 (12.50%)	1 / 8 (12.50%)	1 / 12 (8.33%)
occurrences (all)	5	3	3
Back pain			
subjects affected / exposed	3 / 40 (7.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Myalgia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 8 (12.50%)	1 / 12 (8.33%)
occurrences (all)	1	6	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	11 / 40 (27.50%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	12	0	1
Hypoalbuminaemia			
subjects affected / exposed	5 / 40 (12.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	5	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Hypokalaemia			
subjects affected / exposed	7 / 40 (17.50%)	0 / 8 (0.00%)	1 / 12 (8.33%)
occurrences (all)	7	0	1
Hypophosphataemia			
subjects affected / exposed	6 / 40 (15.00%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	11	0	0
Hypomagnesaemia			
subjects affected / exposed	3 / 40 (7.50%)	0 / 8 (0.00%)	0 / 12 (0.00%)
occurrences (all)	5	0	0

Non-serious adverse events	Hepatocellular carcinoma	Metastatic castration-resistant prostate cancer	Ovarian cancer
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	54 / 54 (100.00%)	39 / 39 (100.00%)

Investigations			
Lymphocyte count decreased			
subjects affected / exposed	8 / 12 (66.67%)	21 / 54 (38.89%)	7 / 39 (17.95%)
occurrences (all)	14	42	9
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	16 / 54 (29.63%)	9 / 39 (23.08%)
occurrences (all)	5	30	10
Alanine aminotransferase increased			
subjects affected / exposed	2 / 12 (16.67%)	14 / 54 (25.93%)	9 / 39 (23.08%)
occurrences (all)	2	17	11
Blood bilirubin increased			
subjects affected / exposed	3 / 12 (25.00%)	8 / 54 (14.81%)	3 / 39 (7.69%)
occurrences (all)	4	9	5
Neutrophil count decreased			
subjects affected / exposed	2 / 12 (16.67%)	10 / 54 (18.52%)	3 / 39 (7.69%)
occurrences (all)	3	24	10
Platelet count decreased			
subjects affected / exposed	3 / 12 (25.00%)	11 / 54 (20.37%)	1 / 39 (2.56%)
occurrences (all)	6	32	1
Blood creatinine increased			
subjects affected / exposed	1 / 12 (8.33%)	6 / 54 (11.11%)	2 / 39 (5.13%)
occurrences (all)	4	17	6
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 54 (3.70%)	1 / 39 (2.56%)
occurrences (all)	1	2	1
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	4 / 54 (7.41%)	4 / 39 (10.26%)
occurrences (all)	0	13	4
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)	3 / 54 (5.56%)	2 / 39 (5.13%)
occurrences (all)	0	3	2
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	3 / 54 (5.56%)	1 / 39 (2.56%)
occurrences (all)	0	4	1
Vascular disorders			

Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	14 / 54 (25.93%)	5 / 39 (12.82%)
occurrences (all)	0	43	5
Hypertension			
subjects affected / exposed	3 / 12 (25.00%)	3 / 54 (5.56%)	4 / 39 (10.26%)
occurrences (all)	4	4	4
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	4 / 54 (7.41%)	4 / 39 (10.26%)
occurrences (all)	0	5	4
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 12 (0.00%)	5 / 54 (9.26%)	5 / 39 (12.82%)
occurrences (all)	0	8	8
Tremor			
subjects affected / exposed	1 / 12 (8.33%)	8 / 54 (14.81%)	2 / 39 (5.13%)
occurrences (all)	1	14	3
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	7 / 12 (58.33%)	38 / 54 (70.37%)	36 / 39 (92.31%)
occurrences (all)	19	161	154
Chills			
subjects affected / exposed	1 / 12 (8.33%)	21 / 54 (38.89%)	15 / 39 (38.46%)
occurrences (all)	1	32	54
Fatigue			
subjects affected / exposed	6 / 12 (50.00%)	13 / 54 (24.07%)	14 / 39 (35.90%)
occurrences (all)	6	20	18
Injection site reaction			
subjects affected / exposed	4 / 12 (33.33%)	13 / 54 (24.07%)	19 / 39 (48.72%)
occurrences (all)	7	25	92
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)	20 / 54 (37.04%)	13 / 39 (33.33%)
occurrences (all)	2	25	17
Oedema peripheral			
subjects affected / exposed	2 / 12 (16.67%)	4 / 54 (7.41%)	4 / 39 (10.26%)
occurrences (all)	2	4	4

Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	3 / 54 (5.56%)	1 / 39 (2.56%)
occurrences (all)	0	3	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 12 (25.00%)	31 / 54 (57.41%)	8 / 39 (20.51%)
occurrences (all)	4	52	9
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 12 (8.33%)	12 / 54 (22.22%)	2 / 39 (5.13%)
occurrences (all)	3	38	7
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	4 / 12 (33.33%)	17 / 54 (31.48%)	22 / 39 (56.41%)
occurrences (all)	7	33	43
Nausea			
subjects affected / exposed	2 / 12 (16.67%)	13 / 54 (24.07%)	24 / 39 (61.54%)
occurrences (all)	5	20	36
Diarrhoea			
subjects affected / exposed	3 / 12 (25.00%)	4 / 54 (7.41%)	12 / 39 (30.77%)
occurrences (all)	3	5	15
Constipation			
subjects affected / exposed	1 / 12 (8.33%)	4 / 54 (7.41%)	7 / 39 (17.95%)
occurrences (all)	1	4	8
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 54 (0.00%)	10 / 39 (25.64%)
occurrences (all)	1	0	10
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 12 (25.00%)	1 / 54 (1.85%)	6 / 39 (15.38%)
occurrences (all)	3	1	8
Cough			
subjects affected / exposed	1 / 12 (8.33%)	2 / 54 (3.70%)	3 / 39 (7.69%)
occurrences (all)	1	2	3
Endocrine disorders			

Hypothyroidism			
subjects affected / exposed	1 / 12 (8.33%)	6 / 54 (11.11%)	3 / 39 (7.69%)
occurrences (all)	2	6	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)	4 / 54 (7.41%)	1 / 39 (2.56%)
occurrences (all)	2	6	1
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	4 / 54 (7.41%)	2 / 39 (5.13%)
occurrences (all)	1	4	2
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	3 / 54 (5.56%)	2 / 39 (5.13%)
occurrences (all)	1	3	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 12 (16.67%)	11 / 54 (20.37%)	10 / 39 (25.64%)
occurrences (all)	2	13	11
Hypoalbuminaemia			
subjects affected / exposed	2 / 12 (16.67%)	6 / 54 (11.11%)	3 / 39 (7.69%)
occurrences (all)	3	9	3
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	12 / 54 (22.22%)	1 / 39 (2.56%)
occurrences (all)	0	19	1
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 54 (5.56%)	2 / 39 (5.13%)
occurrences (all)	0	4	2
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	4 / 54 (7.41%)	0 / 39 (0.00%)
occurrences (all)	0	7	0
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 54 (5.56%)	3 / 39 (7.69%)
occurrences (all)	0	3	4

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 April 2023	-Recruitment to pause during futility analyses -Benefit/risk, recommended phase 2 dose updated -Pharmacokinetics, anti-drug antibody, prostate cancer biomarker, ECG time points reduced -Time window for blood sampling added -Tumor imaging continued at clinical progression -Re-screening; echocardiography or multigated acquisition scanning; up to 3 lines of previous treatment for hepatocellular carcinoma and up to 4 lines for prostate and ovarian cancer; any -mRNA, adenoviral, or inactivated licensed COVID-19 vaccine allowed -Egg and sperm donation, nanrilkefusp alfa monotherapy in the Czech Republic not allowed -Circulating tumor cell count ">5" changed to "≥ 5" -Day 6 blood sampling always performed -Progression-free survival and time to response censoring at "eligibility" changed to "the first day of study treatment" -Treatment concentrations over time in serum not plasma -Fresh biopsy during screening -Exclusion criterion 3 changed to "before study treatment (cycle 1 day 1)" -Exclusion criterion 8.3 changed to "…and any clinically significant history of coronary heart disease and clinically significant artery disease within the past 5 years" -Adverse event terminology according to NCI CTCAE 5.0 - "Whole blood biomarker analysis" row in the table deleted -End of study clarified -Live/attenuated vaccines prohibited 90 days after study treatment -Serology testing mandatory -Cytokine release syndrome, shortening of the QT interval, injection site reaction, hypothyroidism and myocarditis associated with pembrolizumab, fever prevention, toxicity management -recommendations -Information about SUSAR reporting, nanrilkefusp alfa application -Instructions for reporting of certain liver adverse events -Study investigator to obtain consent from pregnant patients -Specification of populations as per national competent authorities' or ethics committees -Biochemistry on cycle 3 day 8 -Pregnancy test until the end of contraception

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None reported

Notes: